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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,088	10/21/2003	Shigeki Hibi	1056-0125P	6122

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EXAMINER

OWENS, AMELIA A

ART UNIT PAPER NUMBER

1625

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/689,088

**Applicant(s)**

HIBI ET AL.

**Examiner**

Amelia A. Owens

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-11 is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1,2 have been canceled. Claims 3-22 are pending.

#### *Restriction*

2. Applicants election with traverse of group I, claims 1-11 is affirmed. Applicants traverse the restriction on the grounds that the search of entire application can be made without serious burden. This is not found persuasive for the reasons of record. Accordingly, claims 12-14 remain withdrawn as being directed to nonelected subject matter.
3. Per applicants' remarks, the method claims 15-22 of group IV have been rejoined. The methods have been examined.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating depression and anxiety, does not reasonably provide enablement for prevention of any of the named disease states including preventing depression and/or anxiety. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the factors have been considered but only the most relevant will be discussed below.

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**The nature of the invention:** The nature of the invention is a therapeutic or prophylactic agent for disease associated with CRF; a therapeutic or prophylactic agent for treatment of the myriad of named diseases. See claims.

**The state of the prior art and predictability:** The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). The disclosure of the present invention is a method of treating and preventing disease associated with CRF wherein compounds of claim 1 are administered to a subject. Corticotrophin-releasing factor (CRF) has been implicated in treating depression and anxiety. See abstract - Arborelius et al, The role of corticotrophin-releasing factor in depression and anxiety disorders, J. of Endocrinology (1999) 160:1-12. Arborelius et al further teaches that there are two (2) CRF receptors at page 2, 2<sup>nd</sup> paragraph. The reference cited by applicant. 'Prophylactic' is the same as preventing. It is not seen where the art teaches prevention of disease states associated with CFR. Hence, the amount of guidance presented in the specification; the absence of data indicating that the claimed disease do not occur when the claimed compounds are administered; , and the state of the prior art indicating that treatment of CRF diseases states, particularly depression and anxiety is possible, all indicate that treatment, not prevention of CRF diseases is possible.

WO 00/59908 teach structurally removed compounds as CRF antagonists useful to treat many of the same diseases applicants are treating. See pages 13-14. The skilled artisan would have no basis to extrapolate results to compounds structurally removed from the tested compounds.

**Guidance and working examples:** Compounds according to the invention have been made. The tests at pages 233-242 are noted. Which receptor are applicants antagonizing, CFR1 or CFR2? It is noted that the data in Table 2 at page 237 is limited to CRF1. No functional assays for in vivo or in vitro procedures regarding the CRF2 receptor are described.

**Quantitation of experimentation:** The amount of guidance necessary to perform applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous disease states to determine which ones, of any, could be prevented by administering claimed compound. Further, the skilled artisan would have to determine which

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receptor is being antagonized, CRF1 or CRF2. Since insufficient teaching and guidance are provided by the specification (as outlined above), the skilled artisan, even with high degree of skill, would not be able to use the claimed compounds without undue experimentation.

***Duplicate Claims***

4. Claims 15 and 16 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. The recitation of the use of the compound in claims 15,16 does not further limit the compound of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

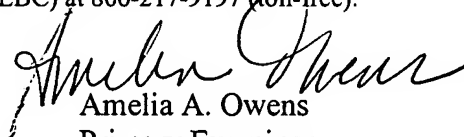
***Allowable Subject Matter***

5. Claims 3-11 are allowed. The prior art neither teaches nor suggests the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Amelia A. Owens  
Primary Examiner  
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